Docket No. 98N-0044

BEFORE THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR RECONSIDERATION

AND

PETITION FOR STAY OF ACTION

BY THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

FINAL RULE CONCERNING REGULATIONS ON STATEMENTS MADE FOR DIETARY SUPPLEMENTS CONCERNING THE EFFECT OF THE PRODUCT ON THE STRUCTURE OR FUNCTION OF THE BODY

February 7, 2000

98N-0044

PRC 4

Pursuant to 21 C.F.R. § 10.33 ("Administrative reconsideration of action") and 21 C.F.R. § 10.35 ("Administrative stay of action"), the undersigned, American Herbal Products Association ("AHPA"), submits this petition to request a stay and reconsideration of the provisions regarding the implementation plan (65 Fed. Reg. at 1044) and the regulation of dietary supplement claims derived from nutritive value (65 Fed. Reg. at 1033) that are set forth in the preamble to the regulations promulgated January 6, 2000, in the above-captioned docket. 65 Fed. Reg. 999. The relief requested is that dietary supplement products labeled in accordance with 21 U.S.C. § 343(r)(6) prior to the regulations' effective date be permitted to continue to be labeled until the implementation dates and that inventoried products with such labels affixed be permitted to be distributed after the implementation dates. In addition, AHPA requests that the "regulation" regarding nutritive value derived structure/function claims for dietary supplements be stayed and withdrawn for failure of compliance with the Administrative Procedure Act.

AHPA is the national trade association and voice of the herbal products industry, which is comprised of domestic and foreign companies doing business as importers, growers, manufacturers, and distributors of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products which contain herbs and which are used to enhance health and quality of life.

A. Decision involved

In the Federal Register of January 6, 2000, 65 Fed. Reg. 999, FDA Docket No. 98N-0044, the Food and Drug Administration ("FDA") published final regulations establishing new requirements for statements made for dietary supplements concerning the effect of the product on the structure or function of the body, 21 C.F.R. § 101.93(f) & (g). These regulations become effective February 7, 2000, 65 Fed. Reg. 999 (2000). In the Implementation Plan for these regulations, FDA stated as follows:

> . . . , all manufacturers will have 11 months after the effective date of the final rule to come into compliance, and small businesses will have 17 months after the effective date of the final rule. The agency believes that these compliance periods, uniformly applied, are sufficiently long that it is not necessary to extend the effective date to 6 months after publication in the **Federal Register.**

AHPA requests that this part of the implementation plan be reconsidered and stayed, and that after reconsideration, this provision be amended to state that products properly labeled pursuant to 21 U.S.C. § 343(r)(6) prior to the regulations' implementation ("come-into-compliance") date be permitted to be distributed after the eleven and seventeen month come-into-compliance periods, even if such labels are affixed to products after the regulations' effective date.

In addition, the preamble to the Final Rule contains a new "regulation" (but one not actually codified in the final regulations) where FDA states that dietary supplements are precluded from being "food" for purposes of 21 U.S.C. § 321(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") so that any structure/function claims made for a dietary supplement, even those derived from the supplement's nutritive value, must comply with 21 U.S.C. § 343(r)(6) of the Act to avoid having the product classified as a drug. 65 Fed. Reg. at 1033. AHPA requests that this "regulation" be withdrawn and that FDA follow the requirements of the Administrative Procedure Act if it is to be made FDA policy.

B. Action requested

In the Federal Register of January 6, 2000, 65 Fed. Reg. 999, FDA published a final regulation entitled Final Rule on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. In its implementation plan for these new regulations, FDA has provided all manufacturers eleven months after the regulations' effective date (February 7, 2000) to come into compliance and small businesses seventeen months to do

the same. No provision is made for the continued distribution of pre-effective date labeled product after the come-into-compliance period. AHPA requests that such distribution be provided for. In addition, FDA has promulgated a new "regulation" regarding nutritive value-based structure/function claims without providing notice and opportunity for comment. AHPA requests this "regulation" be withdrawn.

C. Statement of grounds

1. The Implementation Plan Should be Changed to Allow for the Continued Distribution of Lawfully Labeled Dietary Supplements.

It is AHPA's position that the implementation plan for the structure/function claim regulations which become effective today, February 7, 2000, should not be applied to products which now bear labeling which is presently in compliance with 21 U.S.C. § 343(r)(6)(i.e., those for which unobjected-to notifications have been made to FDA and which bear the required disclaimer) and that such products be permitted to be labeled until the regulations come-into-compliance implementation date and to be shipped thereafter so long as the label had been affixed to the product prior to that date.

The reason for this request is that it will take the time provided for in the come-into-compliance period for companies to change existing lawful labeling. Moreover, manufacturers last year incurred substantial costs coming into compliance with supplement facts labeling requirements. Allowing more time to make changes in labels that were in compliance until the regulations at issue here were published one month ago is wholly reasonable under these circumstances. Indeed, this was the course chosen by FDA when the supplement facts regulations became effective in 1997. There, FDA stated that: "in response to the directive in the DSHEA that dietary supplements 'be labeled' after December 31, 1996, and consistent with the approach taken by Congress in the 1990 amendments, the agency advises that the effective date of this regulation . . . will apply to the attachment of labels to dietary supplement products rather

than to the introduction of products into interstate commerce . . . .". 62 Fed. Reg. at 49842 (Sept. 23, 1997).

Here, FDA has taken a substantially different approach:

> IV. Implementation Plan
>
> The preamble to the proposed rule discussed FDA's tentative conclusions regarding the effective date of a final rule and the agency's implementation plan. In general, the preamble to the proposed rule stated that a final rule would become effective 30 days after the date of the final rule's publication in the Federal Register. Any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, will be expected to be in compliance beginning 30 days after publication of the final rule. However, small businesses that marketed a product as of the date of publication of a final rule would have had an additional 17 months to bring existing claims (i.e., claims already in the product's labeling on January 6, 2000 for those products into compliance, provided that the small business had notified FDA of the claim as required by section 403(r)(6) of the act and Sec. 101.93(a) and that FDA had not objected to the claim. For all other products that were on the market as of the date of publication of a final rule, FDA would have allowed an additional 11 months beyond the effective date to bring existing claims for those products into compliance, provided that the firm had notified FDA of the claim as required by section 403(r)(6) of the act and Sec. 101.93(a) and that FDA had not objected to the claim. Any product marketed for the first time after the date of publication of the final rule, and any new claim made for an existing product for the first time after publication of the final rule, would have been expected to be in compliance beginning 30 days after the date of publication of a final rule.
>
> (112.) Two comments suggested extending the compliance period to 6 months after the date of publication of a final rule. The comments also advocated that there be no distinction between large and small businesses for compliance dates. The comments further suggested that FDA give businesses whose products were on the market as of the date of publication of a final rule 15 months (instead of 11 or 17 months) to comply. Another comment suggested that the final rule

become effective 12 months, rather than 30 days, after its publication date.

FDA believes that the proposed compliance periods of 11 and 17 months following the effective date of the final rule are reasonable and fair, and that the distinction between large and small businesses is appropriate. FDA has decided, however, that it will not treat manufacturers who have not notified the agency of their claims differently from other manufacturers. At least some of those manufacturers who did not submit 30-day notifications to the agency may have failed to do so believing that notification was not necessary under section 201(g)(1)(C) of the act. Therefore, all manufacturers will have 11 months after the effective date of the final rule to come into compliance, and small businesses will have 17 months after the effective date of the final rule. The agency believes that these compliance periods, uniformly applied, are sufficiently long that it is not necessary to extend the effective date to 6 months after publication in the Federal Register.

For a limited transition period, FDA does not intend to take enforcement action against firms who have relied on the agency's September 1997 preamble statements to make a structure/function claim for a dietary supplement under section 201(g)(1)(C) of the act. To allow a reasonable time for the necessary label changes, the transition period will last until the applicable compliance date for the rest of the rule; i.e., small businesses will have 18 months from publication to comply, and other firms will have 12 months. As of the applicable compliance date, firms that have been making structure/function claims under section 201(g)(1)(C) must either remove the claim or comply with the requirements of section 403(r)(6) of the act and Sec. 101.93, including notifying FDA of the claim and relabeling to add the required disclaimer. New structure/function claims are not subject to this transition period; any firm that makes a structure/function claim in the labeling of a dietary supplement after the effective date of this rule must comply with section 403(r)(6) of the act and Sec. 101.93. [65 Fed. Reg. at 1044.]

It is AHPA's position that FDA should not require that labels that were lawful on February 6, 2000, be used between now and the regulations implementation date only under the risk that product in inventory on the come-into-compliance date will need to be destroyed or

overlabeled on that date. There is no principled basis to distinguish the implementation scheme for these labeling regulations from those promulgated in 1997 regarding supplement facts. Accordingly, AHPA respectfully requests that the relief it requests on this subject be granted.

2. Lack of Notice and Opportunity For Comment Invalidates the "Regulation" on Nutritive Value-Based Structure/Function Claims.

The Administrative Procedure Act ("APA") requires that a general notice of proposed rulemaking be "published in the Federal Register... [and] include... either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). After such notice is provided, the APA's rulemaking provisions require that "the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation." 5 U.S.C. § 553(c).

Neither the proposed rule nor the preamble to the proposed rule provided notice that FDA was considering a regulation nutritive value-derived structure function claims. The preamble to the final regulation states as follows:

> A. Scope of Section 403(r)(6) of the Act
>
> 1. Relationship Between Sections 403(r)(6) and 201(g)(1)(C) of the Act
>
> (95.) Several comments stated that the proposal mistakenly suggests that there is only one type of structure/function claim that may be used for dietary supplements. Some of these comments said that if a structure/function claim does not trigger drug status for the product and is not a health claim, then such a claim may be made in labeling for a dietary supplement so long as it is truthful and not misleading. These comments asserted that such a claim is not subject to the notice, labeling, or disclaimer requirements in section 403(r)(6) of the act. As an example, the comments said the claim that ``calcium helps build strong bones'' is not a health claim because it does not characterize a

relationship between the substance and a disease, damage, or dysfunction of the body. The comments added that FDA recognized this in the final rule that it published in the Federal Register on September 23, 1997 (62 FR 49859, 49860, 49863, and 49864), when it stated in the preamble that claims that cranberry juice cocktail helps maintain urinary tract health or that calcium builds strong bones and teeth are not health claims because no disease is mentioned explicitly or implicitly. Some comments added that FDA cannot say that only those claims falling under section 406(r)(6) of the act are structure/function claims because such a result would be contrary to the act and would mean that the proposed rule must be withdrawn.

FDA agrees with these comments in part and disagrees in part. The agency agrees that statements such as ``calcium helps build strong bones'' are not health claims because they do not characterize the relationship between a substance and a disease or health-related condition. Rather, such statements are structure/function claims authorized by section 403(r)(6) of the act.

FDA does not agree with the comment's statement that dietary supplements may bear structure/function claims without complying with the notice, disclaimer, and other requirements of section 403(r)(6) of the act. Section 403(r)(6) of the act, by its terms, applies to dietary supplements. The other possible source of authority to make structure/function claims on dietary supplements is section 201(g)(1)(C) of the act, which provides that ``articles (other than food) intended to affect the structure or any function of the body of man or other animals'' are drugs. Under this provision, foods may make claims to affect the structure or function of the body without being regulated as drugs. By its terms, however, section 201(g)(1)(C) of the act exempts a dietary supplement that bears a structure/function claim from drug regulation only if it is also a food. The last sentence of section 201(ff) of the act provides, ``Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.'' The clear import of this language is that dietary supplements are not foods under section 201(g) of the act and therefore cannot qualify for the ``(other than food)'' exception to the drug definition in section 201(g)(1)(C). As a result, dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the act and are therefore subject to the

> disclaimer, notification, and other requirements in that section and in FDA's implementing regulation.
>
> The agency acknowledges that it took a contrary position in the September 1997 final rule preamble referred to in the comment. In that preamble, FDA said that a dietary supplement could bear a structure/function claim under the ``(other than food)" exception to the definition of ``drug" in section 201(g)(1)(C) of the act, provided that the claim was truthful, non-misleading, and derived from nutritive value (see 62 FR 49859 at 49860, 49863, and 49864). However, the agency has now reconsidered in light of the plain language of section 201(ff) of the act and is revoking its statements on this subject in the September 1997 preamble (i.e., the statements at 62 FR 49859 at 49860, 49863, and 49864 concerning structure/function claims for dietary supplements under section 201(g)(1)(C)). It should be noted, however, that the agency is not revoking its statements in that preamble concerning structure/function claims for conventional foods under section 201(g)(1)(C) of the act. As explained in the September 1997 preamble (62 FR 49859 at 49860), conventional foods may make structure/function claims under section 201(g)(1)(C) of the act as long as such claims are truthful, non-misleading, and derive from the nutritive value of the food. [65 Fed. Reg. at 1033.]

In the April 28, 1998 proposal that led to these final regulations, the nutritive value-based structure/function claims issue was never raised. Nor was it raised at FDA's public meeting convened in August 1999 to discuss the proposal. The failure to provide any indication that a "regulation" regarding nutritive value-based structure/function claims was under consideration deprived interested parties of adequate notice and opportunity for comment on this important matter and violated the APA's rulemaking provisions.

FDA previously had taken the position that nutritive value-based structure/function claims could be made under 21 U.S.C. § 321(g)(1)(C) without following the notification and disclaimer requirements of 21 U.S.C. § 343(r)(6). In the preamble to the final rule on Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements, 62 Fed. Reg. 49859 (1997), FDA stated that:

> The agency agrees that the disclaimer provided for in section 403(r)(6) of the act is required only when the manufacturer wishes to take advantage of the exception from the drug definition that is provided for in section 201(g)(1) of the act for products that comply with section 403(r)(6). Section 201(g)(1)(C) of the act recognizes that common sense foods, that is, products with nutritional value, affect the structure or function of the body because of their nutritional value. Thus, the types of claims described in section 403(r)(6)(A) of the act can be made to describe the nutritive value of a product without fear of action against the product as a drug (e.g., "calcium builds strong bones and teeth") so long as the claims are not false or misleading.
>
> Dietary supplements have to comply with section 403(r)(6) of the act to be subject to the exception (unless, of course, as stated above, they are subject to the other exception for "food" as that term has been interpreted by the courts, *see Nutrilab Inc. v. Schweiker*, 713 F.2d. 335, 338 (7th Cir. 1983)). [62 Fed. Reg. at 49863, 49864.]

Having provided no notice whatsoever that this new "regulation" regarding nutritive value-based-structure/function claims would be considered, much less imposed, FDA is now required by law to withdraw the "regulation" and, if the FDA continues to consider that it properly implements of the FFDCA, to do so in accordance with law.

In Small Refiner Lead Phase-Down Task Force v. Environmental Protection Agency, the District of Columbia Circuit Court of Appeals noted that "[An agency] undoubtedly has authority to promulgate a final rule that differs in some particulars from its proposed rule.... However, if the final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal." 705 F.2d 506, 546-547 (D.C. Cir. 1983). The test for whether sufficient notice and opportunity for comment has been provided is whether the final rule is a "logical outgrowth" of the proposed rule. See, e.g., National Mining Association v. Mine Safety and Health Administration, 116 F.3d 520, 531 (D.C. Cir. 1997); Shell Oil Company v.

Environmental Protection Agency, 950 F.2d 741, 751 (D.C. Cir. 1991). Courts evaluate whether a final rule is the "logical outgrowth" of the proposed rule by "asking whether 'the purposes of notice and comment have been adequately served.'" American Water Works Association v. Environmental Protection Agency, 40 F.3d 1266, 1273 (D.C. Cir. 1994). In Small Refiner, the D.C. Circuit identified the important purposes of the APA's notice and comment requirements, including that notice: (i) "improves the quality of agency rulemaking by ensuring that agency regulations will be 'tested by exposure to diverse public comment'"; and (ii) "is an essential component of 'fairness to affected parties.'" 705 F.2d at 547. Further, notice is "inadequate when 'the interested parties could not reasonably have 'anticipated the final rulemaking from the draft [rule].' ' " National Mining Company, 116 F.3d at 531.

Interested parties could not reasonably have anticipated that the final rule that is the subject of this petition would reverse FDA's previously stated position regarding nutritive value-based structure/function claims because the FDA's proposed structure/function claim regulation addressed only the nature of, and not the derivation of, structure/function claims. While FDA may have decided in the final rule that the FFDCA requires it to regulate nutritive value-based dietary supplement claims in the same fashion as all other dietary supplement claims, it may not do so without providing notice and opportunity for comment so that it may consider the views of interested parties as required by the Administrative Procedure Act. Thus, while FDA's new "regulation" regarding nutritive value-based structure/function claims does involve structure/function claims, it is not "a 'logical outgrowth' that the public should have anticipated." Shell Oil, 950 F.2d at 751. Therefore, "[w]hile petitioners [for judicial review] must show that they would have submitted new arguments to invalidate rules in the case of certain procedural defaults, such as an agency's failure to provide access to supplemental studies, petitioners need not do so

here, where the agency has entirely failed to comply with notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." Shell Oil, 950 F.2d at 752.

D. Conclusion

AHPA requests that FDA reconsider the implementation plan for the structure/function claim regulations as set forth herein. In addition, AHPA requests that the nutritive value-based structure/function claim regulation be withdrawn and that it not be reinstated until the requirements of the Administrative Procedure Act have been met.

Respectfully submitted,

Anthony L. Young
Piper Marbury Rudnick & Wolfe, LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036
(202) 861-3882
Regulatory Counsel for the
American Herbal Products Association

Mr. Michael McGuffin
President
American Herbal Products Association
8484 Georgia Avenue
Suite 370
Silver Spring, MD 20910
301/588-1171

AMERICAN HERBAL PRODUCTS ASSOCIATION

00 FEB -9 P1:37

E-MAIL / FACSIMILE TRANSMITTAL SHEET

TO:	COMPANY:
Ginny Butler	FDA
NUMBER:	DATE:
fax: (301) 827-6870	February 9, 2000
RE:	TOTAL NO. OF PAGES INCLUDING COVER:
Petition signature	3

Dear Ms. Butler,

Here follow the title page and the signature page (page 11 of 11) of the Petition for Reconsideration and Petition for Stay of Action filed by the American Herbal Products Association on February 7, 2000 pursuant to Docket No. 98N-0044.

Feel free to call if you have any additional questions. I can be reached for the next several days at (310) 745-8401.

Yours,

Michael McGuffin
President, American Herbal Products Association

8484 Georgia Ave., Suite 370 Silver Spring, MD 20910
ph: (301) 588-1171 fax: (301) 588-1174

Docket No. 98N-0044

BEFORE THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PETITION FOR RECONSIDERATION

AND

PETITION FOR STAY OF ACTION

BY THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

FINAL RULE CONCERNING REGULATIONS ON STATEMENTS MADE FOR DIETARY SUPPLEMENTS CONCERNING THE EFFECT OF THE PRODUCT ON THE STRUCTURE OR FUNCTION OF THE BODY

February 7, 2000

here, where the agency has entirely failed to comply with notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." Shell Oil, 950 F.2d at 752.

D. Conclusion

AHPA requests that FDA reconsider the implementation plan for the structure/function claim regulations as set forth herein. In addition, AHPA requests that the nutritive value-based structure/function claim regulation be withdrawn and that it not be reinstated until the requirements of the Administrative Procedure Act have been met.

Respectfully submitted,

Anthony L. Young
Piper Marbury Rudnick & Wolfe, LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036
(202) 861-3882
Regulatory Counsel for the
American Herbal Products Association

Mr. Michael McGuffin
President
American Herbal Products Association
8484 Georgia Avenue
Suite 370
Silver Spring, MD 20910
301/588-1171

Butler, Jennie C

From: Katz, Judy - DC [judy.katz@piperrudnick.com]
Sent: Monday, February 07, 2000 2:52 PM
To: 'FDA Docketing'
Subject: Docket No. 98N-0044


5GC001!.DOC

Please accept for filing the enclosed Petition for Stay and Reconsideration by American Herbal Products Association in the above referenced Docket No.

<<5GC001!.DOC>>

The e-mail address and domain name of the sender changed on November 1, 1999. Please update your records.
